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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,577	11/18/2003	Karen Giroux	01435.062US1	6252

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/716,577	GIROUX, KAREN	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58 and 80-82* is/are pending in the application.

4a) Of the above claim(s) *8,12,16,28,46,50 and 54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *1-7,9-11,13-15,17-27,29-45,47-49,51-53,55-58 and 80-82* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/7/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of IDS filed 1/7/09, power of attorney filed 2/10/09, compliant amendment and remarks filed 2/10/09. Claims 59-79 are canceled. New claims 80-82 are added. Claims 1-58 and 80-82 are pending.

Response to Arguments

Previous rejections under 35 USC 103 over Sirhan et al. (WO 2002/056790) that are not reiterated herein are withdrawn because Sirhan teaches the thickness of the coating. Therefore, applicant's arguments with respect to the rejections under 35 USC 103 are moot.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 6, 7, 9, 44, 45 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 6 is dependent on claim 1. Claim one does not recite the presence of a second active agent. Claim 6 says that a second active agent is dissociated from the first polymer upon hydrolysis. It is unclear how a second active agent that has not been previously indicated as

being present in claim 1 dissociates from the polymer of claim 1. Similarly, claim 39 upon which claim 44 depends does not have a second active agent.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-5, 10, 14, 18, 21, 38, 39, 40-43, 48, 49, 52 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Uhrich (WO 9912990).

7. Uhrich discloses medical device such as stent or vascular graft (page 8, line 36 and page 9, lines 1-4) comprising a coating comprising polyanhydride polymer having active agent in the backbone of polymer so that the polymer releases the active agent upon degradation (abstract; page 2, lines 16-31; pages 3-6); the active agents are salicylates , non steroidal anti-inflammatory naphthyl or phenyl propionate (page 2, line 33 to page 3, line 2; page 9, line 5 to page 11, line 36). In another embodiment, The aromatic polyanhydrides may also be combined with quantity of biologically active compounds by physically admixing, embedding or dispersing the agent in the matrix (page 5, line 29 to page 6, line 6; page 11, lines 16-28) and the biologically active agents are acyclovir, cephradrine, malphalan, procaine, ephedrine, adriamicin, daunomycin, plumbagin, atropine, quinine, digoxin, quinidine, biologically active peptides, chlorine, cephadrine, cephalothin, penicillin IV, nicotinic acid, chemodeoxycholic acid, chlorambucil, and others (page 11, lines 29 to page 12, line 9). The stent meets the medical device of claims 1-5,

18 and in general the medical devices of the claims; and, when the stent comprises the polyanhydride having active agent such as salicylate/salicylic acid in the backbone claims 39, 42, 43 are met. When the active agent is salicylic acid, claims 10, 42 and 43 are met. The biological agents dispersed or physically mixed or embedded in the polymer meets the limitation of the second active agent of claims 10, 14, 48 and 52. Claims 21 and 58 are the properties of the coated stent. When the biologically active agent is covalently attached to the aromatic polyanhydride polymer (Uhrich at page 11, lines 19 and 20), then claim 38 is met.

8. Claims 1-5, 10, 11, 13-15, 17-27, 29-43, 48, 49, 51-53, 55-58, 80 and 82 are rejected under 35 U.S.C. 102(a) as being anticipated by Sirhan et al. (WO 2002/056790).

9. Sirhan discloses medical devices such as vascular stents and grafts (page 1, para. 2) for delivery of active agent that includes anti-inflammatory agent and others such as antiproliferatives, antivirals, antineoplastics and combinations (page 20, para. [82]), and specifically the release rate and the duration of the release (page 4, para. 15, 16; page 8, para. 28 and 29; page 20, para 82; page 13, para 51). Sirhan teaches that the therapeutic agent is associated at least in part with the structure that is indirectly or directly coupled to the device in configurations (page 6, para. 23) that include the therapeutic agent being part of the polymer coating the device. Specifically, Sirhan teaches therapeutic capable agents such as the ones referred to above to be associated with expandable structures in the form of a stent having surfaces (page 5, para. [0020]; para. [0021], line 13). The therapeutic capable agents are polymeric material that contain therapeutic capable agents that are linked together by suitable linkages that dissociates to release the subunits of the agent in contact with tissue or fluid (page 8, para.[30]; page 29, para. [113]) and the agents are mycophenolic acid/adipic or mycophenolic

acid/aspirin and/or adipic (para. [30]), some other specific therapeutic capable agents are rapamycin, methotrexate, camptothecin, TACROLIMUS, prednisolone, GEMCITABINE and combinations (page 21, para. [83]). Another therapeutically capable agent may act in synergy with the therapeutic capable agent or agents (page 11, para. [41]), the another therapeutically capable agent is selected from anti-cancer agents, chemotherapeutic agents, thrombolytics, vasodilators, antimicrobials, biologic agents, acetylsalicylic acid, antimicrobials or antibiotics, antimitotics and others named at page 11, para. [42]. Sirhan contemplates employing second compound that may be the same as the therapeutic capable agent of the device and the second compound are mycophenolic acid, rapamycin and their respective pro-drugs, metabolites, derivatives and combinations (page 17, para. [65]; page 41, para. [161]). In some embodiments, the device comprises multiple layers (see the whole document with emphasis on paragraphs [48], [49], [129]) and the thickness of the coat is at from about 0.01 μm to about 100 μm, with a preferred range of from about 0.1 μm to about 50 μm (page 42, para. [162]).

10. The stent of Sirhan meets medical devices of claims 1-5, 18, 22-26, 29-31, 34, 38, 80 with the therapeutic capable agents such as the anti-inflammatories, salicylic acid, the antibiotics, methotrexate meeting the requirements for active agents incorporated into the polymer backbone required by claims 1-5, 10, 13, 14, 17, 26, 29, 31, 33, 34, 39, 42, 43, 48, 51, 52, 55, 80 and 82. When the second compound is the same as the therapeutic capable agent, claims 7, 11, 15, 23, 27, 45, 49 and 53 are met. Coating thickness of from about 0.01 μm to about 100 μm or of from about 0.1 μm to about 50 μm is the species of the recited genus of thickness of 0.1 μm to 10,000 μm (100 nm to 1 cm) or 0.5 μm to 2,000 μm (0.5 μm to 2.0 mm) so that the species anticipating the genus meets claims 19, 20, 35, 36, 56 and 57. Claims 21, 37, 48 and 58 recite the properties

of the device and the claims are thus met. When the therapeutic capable agent is rapamycin, claim 82 is met. Uhrich contemplates the presence of combinations of therapeutic capable agents (page 20, para.[82], another therapeutic capable agent (page 11, para. [42]) and second compound (page 17, para. [65]; page 41, para. [161]) so that the presence of a third active agent is contemplated and thus meets claim 32 with the release of the active agent under physiological conditions being the properties of the device. Further, the device of Uhrich has at least two surfaces (page 5, para. [20], page 6, para. [21], page 7, para. [24], page 12, para. [46], page 14, para. [54], page 15, para. [59]) so that claims 40 and 41 are met.

Response to Arguments

11. Applicant's arguments filed 2/10/09 have been fully considered but they are not persuasive.

12. Applicant argues that no polymer of Sirhan has at least one active agent incorporated into the backbone of the polymer and that the general description in paragraphs [30] and [116] of Sirhan does not describe any devices with enough specificity to anticipate the instant claims.

13. The examiner disagrees. Paragraphs [30] and [113] teach that the "therapeutic capable agent moieties are polymerized and associated to one another through suitable linkages (e. g. ethylenic) forming polymeric therapeutic capable agent. Once the polymeric therapeutic capable agent is brought into contact with tissue or fluid such as blood, the polymeric therapeutic capable agent subunits disassociate. Alternatively, the therapeutic capable agent may be released as the polymeric therapeutic capable agent degrades or hydrolyzes, preferably, through surface degradation or hydrolysis, making the therapeutic capable agent available to the susceptible tissue site, preferably over a period of time." (for paragraph [30]) and "therapeutic capable agent

moieties are polymerized and associated to one another through suitable linkages (e. g. ethylenic) forming polymeric therapeutic capable agent. Once the polymeric therapeutic capable agent is brought into contact with tissue or fluid such as blood, the polymeric therapeutic capable agent subunits disassociate. Alternatively, the therapeutic capable agent may be released as the polymeric therapeutic capable agent degrades or hydrolyzes, preferably, through surface degradation or hydrolysis, making the therapeutic capable agent available to the susceptible tissue site, preferably over a period of time," for paragraph [113]. Thus contrary to applicant's arguments, Sirhan specifically discloses therapeutic capable agents forming polymeric product that dissociate in tissues. Applicant cited paragraph [116] also states that the therapeutic capable agent is a polymeric therapeutic capable agent.

14. Applicant's arguments under 35 USC 103 with regards to the thickness of the coating layer is not persuasive because Sirhan teaches species of coating thickness of from 0.01 μm to about 100 μm or of from about 0.1 μm to about 50 μm (page 42, para. [162]) that anticipates the recited genus of 0.1 μm to 10,000 μm (100 nm to 1 cm) or 0.5 μm to 2,000 μm (0.5 μm to 2.0 mm) for the thickness.

15. With regards to new claims 80 and 82, the examiner disagrees with the applicant that Sirhan does not teach a first polymer in which the backbone is an active agent, a second active agent selected from rapamycin and paclitaxel dispersed within the polymer matrix of the first polymer because Sirhan teaches medical devices that are coated with polymer in which the backbone is an active agent and contemplates the incorporation of a second compound that is selected from mycophenolic acid, rapamycin and their respective pro-drugs, metabolites, derivatives and combinations (page 17, para. [65]; page 41, para. [161]). When the second

compound is rapamycin, claim 82 is met. Claim 81 is rejected under 35 USC 103 over Sirhan in combination with Ragheb, which teaches that medical device coated with composition containing paclitaxel inhibits restenosis, which is also the goal of Sirhan, to reduce restenosis. Therefore, Sirhan anticipates new claims 80 and 82 and renders obvious claim 81 in view of Ragheb.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 1, 11, 15, 19, 20, 22-27, 29, 34, 35, 36, 37, 38, 45, 49, 53, 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uhrich (WO 9912990) in view of Berg et al. (US 5,464,650).

18. Uhrich is described above as anticipating claims 1-5, 10, 14, 18, 21, 38, 39,40-43, 48, 49, 52 and 58. Uhrich does not teach the thickness of the coat as recited by instant claims 19, 20, 35, 36, 56 and 57. But any coating or coat must have some thickness. And Berg discloses coated intravascular stent for delivering active agents such as anti-inflammatory agents (abstract, column 2, lines 55-64); Berg further discloses the amount of drug to be included on the stent is readily controlled by applying multiple thin coats (column 2, lines 44-46) and that the thickness of the coat is variable and suggests that the thickness should be less than 0.002 inch (25.4 μm) and most preferably 0.001 inch (50.8 μm) (column 2, lines 49-51). Therefore, taking the teachings of Uhrich and Berg, one having ordinary skill in the art at the time the invention was

made would reasonably expect to coat the stent by applying thin multiple coats of the polymeric active agent of Uhrich with the expectation of controlling the amount of active agent on the stent so that claims 19, 20, 35, 36, 56 and 57 is met. When the stent is multiply coated by using the same polymeric active agent that comprises salicylic acid anti-inflammatory agent, claims 11, 15, 22-27, 29, 34, 38, 45, 49, 53 are met.

19. Claims 1-5, 10, 11, 13-15, 17-27, 29-43, 48, 49, 51-53, 55-58, 80-82 rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. (WO 2002/056790) in view of Ragheb et al. (US 6,730,064 B2).

20. Sirhan has been described above as anticipating claims 1-5, 10, 11, 13-15, 17-27, 29-43, 48, 49, 51-53, 55-58, 80 and 82. However, while Sirhan teaches the use of anti-neoplastic agents, Sirhan's drug polymer used in the coating does not have paclitaxel as required by claim 81. Specifically, the abstract of Sirhan says that the device is used to reduce restenosis. Ragheb teaches an implantable medical device coated with composition that contains paclitaxel that inhibits restenosis (see claims 1 and 18). Therefore, taking the teachings of Sirhan, one having ordinary skill in the art at the time the invention was made would reasonably expect that including paclitaxel as a specific drug would successfully inhibit restenosis as taught by Ragheb and as contemplated by Sirhan.

21. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Examiner, Art Unit 1618